



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/331,376	06/18/99	FODSTAD	0 7885.65USWO

023552
MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS MN 55402-0903

HM22/0731

EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/331,376

Applicant(s)

Fodstad et al

Examiner
Minh-Tam Davis

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 11, 2001

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-4, 6-11, and 13-16 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4, 6-11, and 13-16 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Application/Control Number: 09/331376

Art Unit: 1642

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-4, 6-11, 13-16 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Rejection under 35 USC 112, second paragraph of claims 6, 8, 11, 13 pertaining to the recitation of cancer antigens wherein claims 6, 8, 11, 13 depend on claim 1, wherein claim 1 excludes malignant cell targets remains for reasons already of record in paper No.13.

Applicant argues that claim 1 excludes both malignant hematopoietic and lymphatic cells and normal hematopoietic and lymphatic cells. However, claim 1 does not exclude all malignant cell targets.

Applicant's arguments set forth in paper No.15 have been considered but are not deemed to be persuasive for the following reasons:

Application/Control Number: 09/331376

Art Unit:

Claim 1 as written reads on exclusion of any malignant cells and normal and haematopoietic and lymphatic cells. This rejection could be obviated by amending the claim, for example, to add "hematopoietic and lymphatic cells" after malignant.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 1-4, 6-11, 13-16 pertaining to lack of enablement for a method to detect and phenotype any normal cells remains for reasons already of record in paper No.13.

Applicant argues that table 1 on page 9 provides a list of specific antigens and their corresponding antibodies that can be used in the claimed method. One would know to choose an antibody that correspond to a known antigen expressed on a particular target cell(s) of interest.

Applicant's arguments set forth in paper No.15 have been considered but are not deemed to be persuasive for the following reasons:

Although table 1 on page 9 recites some adhesion molecules, carbohydrate antigens, glycolipids and growth factor receptors, the specification does not teach how to make antibodies and antigen specific for any normal cells that could distinguish one normal cell from other.

REJECTION UNDER 35 USC 103

Art Unit:

Rejection under 35 USC 103 of claims 1-4, 6-111, 13-16 pertaining to obviousness over Hajek et al, in view of Fodstad et al and O'Briant et al remains for reasons already of record in paper No.13.

Applicant argues that the references by Hajek et al and Fodstad et al disclose fluorescent tagged antibody, whereas in the claimed invention fluorescent or dyed particles are coated with antibodies. Applicant further argues that the claimed invention is directed to cells in suspension, and not cells formed as smears and stained as cited in Hajek et al. Further, the claimed invention provides the advantage of a larger fluorescent or dyed particle, and due to the size of the particle, enjoys fluorescent strength for a considerable amount of time.

Applicant's arguments set forth in paper No.15 have been considered but are not deemed to be persuasive for the following reasons:

The sizes of the microspheres taught by Hajek et al (column 8) is within the range of sizes of the particles in the claimed method. Further, although Hajek et al teach the use of smears on slide for use in fluorescent microscope, Hajek et al also teach that the samples could also be analyzed by flow cytometry instrument (column 2). It is well known in the art, and as recited by Fodstad et al, a cell suspension is used in a flow cytometer (p.5, first paragraph). In addition, Hajek et al teach that different sets of microspheres are optically differentiated by having different optical characteristics such as size, shape, color or combination thereof (abstract, and column 10, lines 20-24).

Art Unit:

Thus the claimed method appears to be the same as the prior art combined method, absent a showing of unobvious differences.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Art Unit:

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

July 20, 2001


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600